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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,914	03/07/2006	Alfred Marchal	09997.0127USWO	9556

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EXAMINER	
VALENROD, YEVGENY	
ART UNIT	PAPER NUMBER
1621	
MAIL DATE	DELIVERY MODE
08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,914	MARCHAL, ALFRED	
	Examiner	Art Unit	
	YEVEGENY VALENROD	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/5/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/5/09 has been entered.

Rejection of claims 1 and 3-10 over Elson et al. in view of Ryall et al. is withdrawn in view of applicants' amendment to the claims.

Applicants' remarks and the Declaration under 37 C.F.R 1.132 have been considered and are addressed following the text of the rejection.

Claim Rejections – 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

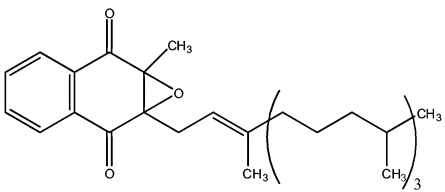
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-10 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Elson (U.S. Patent 5,510,391), in view of Dowd et al. (*J. Am. Chem. Soc.* **1991**, *113*, 7734-7743) and further in view of US 5,981,601 and US 6,180,136.

The instant claims are drawn to a method of treating dermatological lesions of a mammal by using a compound of formula I, as depicted below:



Scope of prior art

Elson teaches that synthetic Vitamin K1 analogs can be used in cosmetic and/or pharmaceutical formulation for use in treating the skin (see column 7, lines 18-20; abstract), as a cream (column 3, line 19-21) at concentrations of 1% and 5% (column 3,

lines 40 and 55). Vitamin K1 oxide would be considered to be a species of the generic teaching of Elson. Elson's formulations treats blood vessel disorders of the skin, including actinic and iatrogenic purpura, lentigines, telangiectasias of the face, spider angiomas, spider veins of the face, spider veins of the legs and other vascular problems of the skin and subcutaneous tissue (column 1, lines 24-31). Additionally, Elson's formulations contain lecithin granules which are composed of lipid particles (abstract).

Regarding claims 4, 5 and 8 which presents limitations as to the particle size of the phospholipids and the percentage of the compound of Formula 1, it is the position of the examiner that one of ordinary skill in the art, at the time of the invention, would through routine and normal experimentation determine the optimization of these limitations to provide the best effective variable depending on the results desired. Thus it would be obvious in the optimization process to optimize the particle size of the phospholipids and the percentage of the compounds. Note that the prior art provides the same effect desired by applicant, the treatment of the same skin conditions.

Difference between prior art and instant claims

Elson is deficient in that it does not teach using Vitamin K1 epoxide as instantly claimed.

Secondary references

Dowd et al teach that the metabolic pathway of vitamin K conducts to vitamin K oxide as the active metabolite.

Obviousness

In view of the prior art, one skilled in the art would find it obvious to utilize vitamin K oxide instead of vitamin K for the treatment of dermatological lesions. Expectation of success in doing so is provided by Dowd et al. Dowd teaches that vitamin K oxide is the active metabolite of vitamin K (this teaching is supported in the applicants Exhibit A under the section Pharmacological aspects). In addition, applicant has indicated that art recognizes cosmetic creams containing vitamin K oxide are more topically active then the vitamin K creams (Exhibit A, under the section Pharmacological aspects lines 7-8).

One of ordinary skill in the art would be motivated to use vitamin K oxide for Elson's formulations, with the reasonable expectation that the compounds would treat dermatological conditions involving blood vessel disorders. The limitations directed to other components of the composition (such as other vitamins) and particular form and type of a composition are obvious absent unexpected results. Prior art recognizes addition of vitamins to pharmaceutical compositions (see for example US 5,981,601, claim 21) and its obvious to formulate a topical composition into a gel lipidic particles (for example US 6,180,136 claim 9), gels, lotions or liquid absent unexpected results arising from the type of the formulation.

The instant claims are therefore obvious over the prior art absent unexpected results.

Reply to applicants' remarks and the declaration under CFR 1.132

Applicant has argued unexpected results. In support applicant has submitted data (part of Exhibit A in the 132 declaration) which indicates that vitamin K oxide has superior properties in reducing bruising. However, instant claims are not limited to bruising but to dermatological lesions in general and the data showed that there is no difference in the ability of vitamin k oxide to reduce swelling compared to vitamin K. The results are therefore not commensurate with the breadth of the claims. It is also in question if the reduction in bruising can be construed to be an unexpected result. Since Dowd teaches that Vitamin K oxide is the active metabolite, administration of the active metabolite can be expected to result in a faster result than of the Vitamin K. Applicant has conceded that art recognizes Vitamin K oxide creams are more topically active than cosmetic vitamin K cream (Exhibit A, under the section Pharmacological aspects lines 7-8). The observed reduction in bruising is therefore not unexpected.

Applicant's remarks concerning inhibition of vitamin K1 epoxide reductase are noted, however since the new rejection does not depend on the function of the vitamin K1 epoxide reductase examiner believes further discussion of this topic would not be productive towards moving forward with the prosecution.

Conclusion

Claims 1 and 3-10 are pending

Claims 1 and 3-10 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yevgeny Valenrod/

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